PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING WHERE THERE IS NO PACKAGE LEAFLET, i.e. Combined label and package leaflet {Securitainer and bucket}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Doxylin, 433 mg/g, Powder for Use in Drinking Water for Chickens and Turkeys

2. COMPOSITION

Doxycycline	433.3 mg/g
(as doxycycline hyclate	500.0 mg/g)

Yellow, crystalline powder

3. PACKAGE SIZE

1 kg, 2.5 kg, 5 kg.

4. TARGET SPECIES

For chickens (broilers, broiler breeders) and turkeys (broilers, breeders).

5. INDICATIONS FOR USE

Indications for use

Treatment of clinical respiratory infections associated with *Mycoplasma gallisepticum* susceptible to doxycycline.

6. CONTRAINDICATIONS

Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use when tetracycline resistance has been detected in the herd/flock due to the potential for cross resistance.
Do not use in animals with hepatic dysfunction.

7. SPECIAL WARNINGS

Special warnings

Special warnings:
The intake of medication by animals can be altered as a consequence of illness. In case of insufficient intake of drinking water, animals should be treated parenterally.

Special precautions for safe use in the target species:
Due to variability (time, geographical) in susceptibility of bacteria for doxycycline, bacteriological sampling and susceptibility testing of micro-organisms from diseased animals on farm are highly recommended.
Use of the veterinary medicinal product deviating from the instructions given on the label may increase the prevalence of bacteria resistant to doxycycline and may decrease effectiveness of treatment with tetracyclines due to the potential for cross resistance.
Use of the veterinary medicinal product should take into account official and local antimicrobial policies.
Avoid administration in oxidized drinking equipment.
As eradication of the target pathogens may not be achieved, medication should therefore be combined with good management practices, e.g. good hygiene, proper ventilation, no overstocking.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
During preparation and administration direct contact of the veterinary medicinal product with the skin, eyes and mucous membranes and inhalation of dust particles should be avoided.
People with known hypersensitivity to tetracyclines should avoid contact with the veterinary medicinal product.
Personal protective equipment consisting of protective gloves (e.g. rubber or latex), glasses and an appropriate dust mask (e.g. disposable half-mask respirator conforming to European Standard EN149 or a non-disposable respirator to European Standard EN140 with a filter to EN143 should be worn when handling the veterinary medicinal product. Wash exposed skin after preparation of medicated drinking water.
In case of accidental eye contact, rinse with plenty of fresh water. Do not smoke, eat or drink when handling the veterinary medicinal product.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician. Inflammation of the face, lips or eyes or respiratory difficulties are the most serious signs which require urgent medical attention.

Pregnancy and lactation:
Laboratory studies in rats and rabbits have not produced any evidence of a teratogenic, foetotoxic or maternotoxic effects.

Interactions with other medicinal products and other forms of interaction:
Do not administer concurrently with feed overloaded with polyvalent cations such as Ca^{2+}, Mg^{2+}, Zn^{2+} and Fe^{3+} because the formation of doxycycline complexes with these cations is possible. Do not administer together with antacids, kaolin and iron preparations as tetracyclines are bacteriostatic antimicrobials, do not administer in conjunction with

bactericidal antibiotics like beta-lactams. It is advised that the interval between administration of other veterinary medicinal products containing polyvalent cations should be 1-2 hours because they limit the absorption of tetracycline.
Doxycycline increases the action of anticoagulants.

Overdose:
During the target animal tolerance study, no adverse effect was observed even at the fivefold therapeutic dose administered for two times the recommended duration in either target animal species.
If suspected toxic reactions do occur due to extreme overdose, the medication should be discontinued and appropriate symptomatic treatment should be initiated if necessary.

Major incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

8. ADVERSE EVENTS

Adverse events

Chickens (broilers, broiler breeders) and turkeys (broilers, breeders):

Rare (1 to 10 animals / 10,000 animals treated):	Allergic reaction Photosensitivity (abnormal skin reaction to light)

If suspected adverse reactions occur, treatment should be discontinued.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed on this label, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation using the contact details on this label, or via your national reporting system at:

Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

e-mail: adverse.events@vmd.gov.uk

9. DOSAGE FOR EACH TARGET SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Dosage for each species, routes and method of administration

To be administered in drinking water.

Chickens: 20 mg doxycycline per kg of body weight daily (equivalent to 46 mg veterinary medicinal product per kg of body weight), administered in the drinking water for 5 consecutive days.

Turkeys: 25 mg doxycycline per kg of body weight daily (equivalent to 58 mg veterinary medicinal product per kg of body weight), administered in the drinking water for 5 consecutive days.

10. ADVICE ON CORRECT ADMINISTRATION

Advice on correct administration

To ensure a correct dosage, body weight should be determined as accurately as possible to avoid underdosing.

The intake of medicated water depends on the clinical conditions of the animals. In order to obtain the correct dosage, the concentration of doxycycline may need to be adjusted accordingly.

The use of suitably calibrated measuring equipment is recommended if part packs are used

Based on the recommended dose, and the number and weight of the animals to be treated, the exact daily amount of product should be calculated according to the following formula:

$$\frac{\text{..... mg veterinary medicinal product per kg body weight per day} \times \text{mean body weight (kg) of animals to be treated}}{\text{mean daily water consumption (litre per animal)}} = \text{.... mg veterinary medicinal product per litre of drinking water}$$

The daily amount is to be added to the drinking water such that all medication will be consumed in 24 hours. Medicated drinking water should be freshly prepared every 24 hours. It is recommended to prepare a concentrated pre-solution - not exceeding 100 grams veterinary medicinal product per litre drinking water - and to dilute this further to therapeutic concentrations, if required. Alternatively; the concentrated solution can be used in a proportional water medicator.

It should be ensured that all animals intended for treatment should have free access to the drinking facilities. At the end of treatment, the watering equipment should be cleaned adequately to avoid the intake of remaining quantities in sub-therapeutic doses. The medicated water should be the only source of drinking water, throughout the treatment period. The medicated water must not be made or stored in a metal container. Solubility of the veterinary medicinal product is pH dependent and it will precipitate if it is mixed in an alkaline solution. In order to ensure a complete and permanent dissolution of the veterinary medicinal product in each water quality, a minimum concentration is required.

The minimum concentration in drinking water is 200 mg veterinary medicinal product per litre. Animals requiring a lower concentration should not be treated with the veterinary medicinal product.

11. WITHDRAWAL PERIODS

Withdrawal periods

Meat and offal:
Chickens: 5 days.
Turkeys: 12 days.
Not authorised for use in birds producing eggs for human consumption.

12. SPECIAL STORAGE PRECAUTIONS

Special storage precautions

Keep out of the sight and reach of children.
Store below 25ºC.
Keep the container tightly closed in order to protect from light.
Medicated drinking water should be protected from light.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp.
The expiry date refers to the last day of that month.

13. SPECIAL PRECAUTIONS FOR DISPOSAL

Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon how to dispose of medicines no longer required.

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 28365/4006

Pack sizes

List of pack sizes:
Securitainer: 1 kg.
Bucket: 1, 2.5, 5 kg.
Not all pack sizes may be marketed.

16. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

17. CONTACT DETAILS

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:

Dopharma Research B.V.
Zalmweg 24
NL-4941 VX Raamsdonksveer
+31-162-582000
pharmacovigilance@dopharma.com

18. OTHER INFORMATION

Other information

POM-V

19. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

20. EXPIRY DATE

Exp {mm/yyyy}

Shelf-life after first opening the immediate packaging: 3 months.
Once opened, use by …
Once dissolved in drinking water, use within 24 hours.

21. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE Securitainer and bucket

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Doxylin, 433 mg/g, Powder for Use in Drinking Water for Chickens and Turkeys

2. STATEMENT OF ACTIVE SUBSTANCES

Doxycycline	433.3 mg/g
(as doxycycline hyclate	500.0 mg/g)

3. PACKAGE SIZE

1 kg, 2.5 kg, 5 kg.

4. TARGET SPECIES

For chickens (broilers, broiler breeders) and turkeys (broilers, breeders).

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

To be administered in drinking water.

7. WITHDRAWAL PERIODS

Withdrawal periods:
Meat and offal
Chickens: 5 days.
Turkeys: 12 days.
Not for use in birds producing eggs for human consumption.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened, use within 3 months.
Once dissolved in drinking water, use within 24 hours.
Once opened, use by …

9. SPECIAL STORAGE PRECAUTIONS

Store below 25 °C.
Keep the container tightly closed in order to protect from light.
Medicated drinking water should be protected from light.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Dopharma Research B.V.

14. MARKETING AUTHORISATION NUMBERS

Vm 28365/4006

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Doxylin, 433 mg/g, Powder for Use in Drinking Water for Chickens and Turkeys

2. Composition

Doxycycline	433.3 mg/g
(as doxycycline hyclate	500.0 mg/g)

Yellow, crystalline powder

3. Target species

Chickens (broilers, broiler breeders) and turkeys (broilers, breeders).

4. Indications for use

Treatment of clinical respiratory infections associated with *Mycoplasma gallisepticum* susceptible to doxycycline.

5. Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use when tetracycline resistance has been detected in the herd/flock due to the potential for cross resistance.
Do not use in animals with hepatic dysfunction.

6. Special warnings

Special warnings:
The intake of medication by animals can be altered as a consequence of illness. In case of insufficient intake of drinking water, animals should be treated parenterally.

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Due to variability (time, geographical) in susceptibility of bacteria for doxycycline, bacteriological sampling and susceptibility testing of micro-organisms from diseased animals on farm are highly recommended.
Use of the veterinary medicinal product deviating from the instructions given in the leaflet may increase the prevalence of bacteria resistant to doxycycline and may decrease effectiveness of treatment with tetracyclines due to the potential for cross resistance.
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Wash exposed skin after preparation of medicated drinking water.
In case of accidental eye contact, rinse with plenty of fresh water. Do not smoke, eat or drink when handling the product.
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Laboratory studies in rats and rabbits have not produced any evidence of a teratogenic, foetotoxic or maternotoxic effects.

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Major incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

7. Adverse events

Chickens (broilers, broiler breeders) and turkeys (broilers, breeders).

Rare (1 to 10 animals / 10,000 animals treated):	Allergic reaction Photosensitivity (abnormal skin reaction to light)

If suspected adverse reactions occur, treatment should be discontinued.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:

Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

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Turkeys: 25 mg doxycycline per kg of body weight daily (equivalent to 58 mg veterinary medicinal product per kg of body weight), administered in the drinking water for 5 consecutive days.

9. Advice on correct administration

Based on the recommended dose, and the number and weight of the animals to be treated, the exact daily amount of veterinary medicinal product should be calculated according to the following formula:

$$\frac{\text{..... mg veterinary medicinal product per kg body weight per day} \times \text{mean body weight (kg) of animals to be treated}}{\text{mean daily water consumption (litre per animal)}} = \text{.... mg veterinary medicinal product per litre of drinking water}$$

To ensure a correct dosage body weight should be determined as accurately as possible.

The intake of medicated water is depends on the clinical conditions of the animals. In order to obtain the correct dosage, the concentration of doxycycline may need to be adjusted accordingly. The use of suitably calibrated measuring equipment is recommended.

The daily amount is to be added to the drinking water such that all medication will be consumed in 24 hours. Medicated drinking water should be freshly prepared every 24 hours. It is recommended to prepare a concentrated pre-solution - not exceeding 100 grams veterinary medicinal product per litre drinking water - and to dilute this further to therapeutic concentrations, if required. Alternatively; the concentrated solution can be used in a proportional water medicator.

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10. Withdrawal periods

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Turkeys: 12 days.
Not for use in birds producing eggs for human consumption.

11. Special storage precautions

Keep out of the sight and reach of children.

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Keep the container tightly closed in order to protect from light.
Medicated drinking water should be protected from light.
Do not use this veterinary medicinal product after the expiry date which stated on the label after Exp.
The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 3 months
Shelf life after dissolution according to directions: 24 hours

12. Special precautions for disposal

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Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 28365/4006

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Bucket: 1, 2.5, 5 kg.
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16. Contact details

Marketing authorisation holder:
Dopharma Research B.V.
Zalmweg 24
NL-4941 VX Raamsdonksveer
The Netherlands
+31-162-582000
pharmacovigilance@dopharma.com

Manufacturer responsible for batch release:
Dopharma B.V.
Zalmweg 24
NL-4941 VX Raamsdonksveer

17. Other information

POM-V

Gavin Hall
Approved: 25 March 2025